DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6880 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
FAX: 504-253-4530

October 21, 2004

WARNING LETTER NO. 2005-NOL-02

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mrs. Lorna M. Peterson, Owner
Willson Instruments for Medicine
121 West Camphor Avenue
Foley, Alabama 36535

Dear Mrs. Peterson:

On July 21, 22, and 28, 2004, a United States Food and Drug Administration (FDA) investigator inspected your firm, located at 121 West Camphor Avenue, Foley, Alabama. FDA has determined your firm is a finished device manufacturer for sterile guide wires. Guide wires are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). You may find the Act and associated regulations through links at FDA's home page at www.fda.gov.

The inspection revealed your devices are adulterated within the meaning of Section 501(h) of the Act, as methods used in, or facilities or controls used for design, manufacturing, packing, labeling, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, *Code of Federal Regulations*, Part 820 (21 CFR 820), as follows:

1. You failed to establish and maintain a quality system appropriate for sterile guide wires to meet requirements of the Quality System regulation (21 CFR 820.5). You are the finished device manufacturer for the sterile guide wires, as well as the specification developer. As such, you are responsible for all functions your firm performs or should perform under 21 CFR 820 and all functions occurring at your contract manufacturer(s). Under these regulations, you are responsible for evaluation of suppliers/contractors; type and extent of control to be exercised over products, services, etc.; and, establishment of clear purchasing data, including quality requirements.

2. You have not established and implemented procedures for the following:

   a. Receiving, reviewing, and evaluating complaints in a uniform and timely manner. In addition, you have no procedure for investigating or evaluating complaints to determine if a Medical Device Report should be filed (21 CFR 803), as required by 21 CFR 820.198.

b. Ensuring all purchased or received products and services conform to specified requirements and addressing evaluation of your suppliers and contractors, including quality requirements. You have no procedures for purchasing or handling changes in products or services to determine whether a change may have an adverse affect on quality of the finished device, as required by 21 CFR 820.50.

The sterile guide wires labeled and distributed by your firm and for which you own the design are manufactured by [redacted] located in [redacted] You have no written procedures for evaluating or handling changes made by [redacted] or changes made by the contract sterilizer to ensure your sterile guide wires are manufactured, sterilized, and received according to your specified requirements. You have no records to document [redacted] or the contract sterilizer have been evaluated within the past five years. You have not defined the type and extent of control to be exercised over the product, services, and suppliers based on any evaluations.

c. Receiving or final acceptance activities nor records documenting these activities, as required by 21 CFR 820.80.

d. Label control, including release of new labeling, product labeling, and label use in device history records, as required by 21 CFR 820.120.

e. Document control, including approval, distribution, and change of documents, as required by 21 CFR 820.40.

f. Handling and storage to prevent mix-ups, damage, deterioration, contamination, or other adverse effects and ensuring no obsolete or deteriorated products are distributed, as required by 21 CFR 820.140 and 150.

g. Ensuring purchase orders are reviewed and only those devices approved for release are distributed. Further, you have no procedure addressing maintenance of any control/lot numbers associated with the finished device, as required by 21 CFR 820.160.

3. You do not maintain device master or history records for sterile guide wires, nor do you have access controlled to those records, if any are maintained at contract manufacturer(s) or supplier(s) in order for you to fulfill your obligations under 21 CFR 820.40, 80, 90, 100, 140, 150, 160 and 198. These documents are necessary for ensuring each lot of sterile guide wires has been manufactured in accordance with specified requirements and regulations, as required by 21 CFR 820.181 and 184.

Your guide wires are misbranded within the meaning of Section 502(o) of the Act, as they were manufactured, prepared, or processed in an establishment not registered under Section 510 and not included in a list required by Section 510(j) of the Act and 21 CFR 807.20. Enclosed are forms for registering your firm and listing your sterile guide wires. More information can be found on FDA's website at www.fda.gov/cdrh/reglistpage.html.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It remains your responsibility to ensure adherence to all requirements of the Act and regulations. The specific

violations noted in this letter and Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining causes of violations identified by FDA, and initiating permanent corrective and preventive actions in your Quality System.

Federal agencies are advised of the issuance of all warning letters about devices so they may take this information into account when considering the award of contracts. Additionally, no requests for Certificates to Foreign Governments will be approved until violations related to subject devices have been corrected.

You should take prompt action to correct these violations. Failure to correct these violations promptly may result in regulatory action by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We are aware you made a verbal commitment, at the close of your inspection on July 28, 2004, to correct observed deficiencies. You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct noted violations, including an explanation of each step taken to identify and make corrections to any underlying systems problems necessary to assure similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, please state the reason for delay and time within which corrections will be completed.

Address your reply to the U.S. Food and Drug Administration, Attention: Cynthia R. Crocker, Compliance Officer, 100 W. Capitol Street, Suite 340, Jackson, Mississippi 39269. If you have questions regarding any issue in this letter, please contact Ms. Crocker at (601) 965-4581, extension 106.

Sincerely,

H. Tyler Thornburg
District Director
New Orleans District

Enclosures: Form FDA 483
21 CFR 820
Form FDA 2891
Form FDA 2892